REMARKS/ARGUMENTS

Claims 1-6, 21, 22, 24-30, 32-40, 58, 60, 63-66, and 68-88 are pending in the present application. Claims 4-6, 33-40, 58, 60, 64-66, 68 and 79-88 are withdrawn. By this Amendment, Applicant has amended certain claims and added new claim 89. Support for the amended claims and new claim can be found throughout the specification and claims as originally filed. Entry and consideration of the amended and new claims presented herein are respectfully requested. Favorable consideration of the pending claims is respectfully requested.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections.

Applicants hereby provide a certified copy of the Australian Application to which foreign priority is claimed. Applicants request acknowledgement of receipt of same.

In the Office Action, the Examiner states that the sequence disclosures fail to comply with 37 CFR 1.821 and 1.825. Applicants have amended the specification to address these concerns, and believe that the sequence disclosures are now fully compliant with 37 CFR 1.821 and 1.825.

Claim Rejections - 35 U.S.C. §112

Claims 1-3, 21, 22, 24-30, 32, 64-66, and 69-78 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

Examiner states that "there is no evidence or suggestion of record that a dsRNA can be used to augment expression of any gene to which it has homology." In addition, the examiner states that "the specification provides no working example of this embodiment." Applicant's contend that the application as filed teaches one skilled in the art how use dsRNA to alter the expression of a gene. Example 6 of the application provides detailed explanation of using

dsRNA mediated gene inhibition. Specifically, this example provides a sequence encoding the Tat protein which can be used (See paragraphs 223-224). In addition, Figure 9C provides a picture of such a sequence. While Applicant's did not specifically include an example of activation of specific gene expression, the application provides details of how to structure such sequences and teaches one skilled in the art how to activate gene expression. Applicant's have included a recent article from Nature Chemical Biology (Nat Chem Biol. 2007 Mar;3(3):166-73.) confirming what Applicant's teach, that dsRNA can be used to activate gene expression. The publication uses similar methods as disclosed in Applicant's application.

Examiner also states that "because Tat is know to inhibit the activity of PKR, it is unclear why one skilled in the art would expect Tat to enhance the ability of dsRNA to negatively affect expression of a target gene." While the examiner is correct that Tat binds to PKR, it has been shown by Endo-Munoz et al (Virol J 2005 Feb 28; 2:17) that during this interaction HIV tat is phosphorylated by PKR and that this phosphorylation increases interaction of Tat with TAR (the tat response element in the HIV long terminal repeat- LTR), thereby enhancing transcription. Example 6 specifically shows how Tat would be used to enhance the effect of dsRNA. Figure 9 shows the construct (Fig 9 C) in which tat is produced by the LTR. Once expressed Tat would then bind to the TAR element in the LTR to enhance expression of the specific dsRNA. Tat activates expression of the HIV LTR by binding to the TAR element in the HIV LTR.

Examiner further states that "the claimed dsRNAs do not provide adequate structure to ensure expression of encoded Tat." Applicant's content most natural mRNAs are highly structured and contain internal dsRNA regions and yet protein translation occurs. Moreover, most pre-mRNAs are processed to remove introns and splice exons for translation. Recently, it has been shown that both dsRNA, effective at targeting specific mRNA, and protein translation could occur from a single transcript (Unwalla HJ, Li HT, Bahner I, Li MJ, Kohn D, Rossi JJ. Novel Pol II fusion promoter directs human immunodeficiency virus type 1-inducible coexpression of a short hairpin RNA and protein. J Virol. 2006 Feb;80(4):1863-73.).

Applicant has provided Examiner with sound scientific arguments and current literature confirming what Applicant teaches. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112 is respectfully requested.

Respectfully submitted,

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